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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,447	07/10/2003	Tae-Woon Kim	LEELE82.001C1	4213

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EXAMINER	
UNDERDAHL, THANE E	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	12/22/2006	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 12/22/2006.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/618,447	KIM ET AL.	
	Examiner	Art Unit	
	Thane Underdahl	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *14-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/5/04, 2/17/04, 12/1/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Restriction/Election

Applicant's response to the species election without traverse filed on 11/1/06 is acknowledged. The applicant elected Group I which includes claims 1-13. The required species elected in claim 9 of a polyepoxy compound is withdrawn, however the election of species in claim 13 of porcine skin tissue and claim 7 of skin of mammal remain. Claims 1-13 will now be examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 8, 10, 11 and 13 rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al. (WO 94/117841, published 1994).

These claims are drawn to a biomaterial comprising a collagen-based tissue from a mammal and a plurality of crosslinking bonds with polyepoxy compounds. The biomaterial must be decelluralized and substantially free from the cells of the mammal as well as debris from the cells of the mammal. The tissue can be from the skin of a mammal or more specifically porcine skin tissue. The tissue must also comprise a helical structure of polypeptides.

The polyepoxy compounds can comprise 17-25 carbon atoms and 4-5 epoxy groups. They also can be selected from the group of polyglycerol polyglycidyl ether and

polyethylene glycol glycidyl ether. The polyepoxy form crosslinking bonds between with the amino acids on the tissue.

Tu et al. teach a collagen based material obtained from a mammal (page 7, lines 1-10) or more specifically porcine skin (page 19, lines 10-15). The tissue is prepared to substantially decelluralized and free of mammal cells and cellular debris (Tu et al. Examples 1 and 2).

The tissue is fixed by crosslinking the collagen with a variety of polyepoxy compounds such as Sorbitol tetraglycidyl ether (Industrial Name: Denacol Ex-612) which has 18 carbon atoms and 4 epoxy groups. It is inherent that these epoxy groups will form the crosslinking bonds to the amino acids on the collagen. Claim 10 limits the tissue to have a helical structure of polypeptides. Collagen inherently has polypeptide chains in the triple helical confirmation (Tu et al. page 2, lines 1-5)
Therefore the reference anticipates claims 1-4, 7, 8, 10, 11 and 13.

Claims 1, 6, 10, and 11 rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al. (J. of Biomed. Mat. Research, 1994 which will be referred to as JBMR).

These claims are drawn to a biomaterial comprising a collagen-based tissue from a mammal and a plurality of crosslinking bonds with polyepoxy compounds. The tissue must comprise a helical structure of polypeptides. The links between the tissue and the poly epoxy compounds are crosslinking bonds between the compound and amino acids on the tissue. The biomaterial is in a freeze-dried form.

JBMR teach a biomaterial made of thoracic arteries that contain 33% collagen. The collagen containing arteries are the linked with one of several polyepoxy compounds (page 677 col. 2 Materials and Methods to page 678, col. 1, paragraph 1). The epoxy compounds bind to the amino acids on collagen (page 679, figure 1). Also collagen inherently has a triple helical structure of polypeptides. JBMR also lyophilizes (freeze-dried) their biomaterial (page 678, col. 1, paragraph 3).

Therefore the reference anticipates claims 1, 6, 10, and 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. (WO 94/17841) as applied to claims 1-4, 7, 8, 10, 11 and 13 above, and further in view of Watson et al. (U.S. Patent 5,891,617, 1999).

This claim coats the biomaterial of claim 1 with a cryoprotective material.

Tu et al. teach the biomaterial of claim 1 and does indicate the need to preserve the biomaterial (Tu et al. page 10, lines 10-15).

Watson et al. teach a method of immersing and coating harvested tissue in a cryoprotectant solution (col. 4, lines 50-60). Watson et al. teach that their invention is useful for many tissues including collagen (col. 7, lines 20-25). Watson et al. also

provides the motivation by emphasizing the need of Tu et al. by stating "the shelf life of living tissues is limited and...there is a need to preserve such tissues for an extended periods of time, as in shipping and storage until their use" (Watson col. 1, lines 25-35). Watson et al. also provides a reasonable expectation of success by successfully freezing many collagen-containing tissues such as skin components (Watson, Example 1-3) and corneas (Watson, Example 4).

Therefore the references listed above renders obvious claim 5.

Claims 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. (WO 94/17841) as applied to claims 1-4, 7, 8, 10, 11 and 13 above, and further in view of Kelman et al. (U.S. Patent # 4,969,912).

These claims are drawn to the biomaterial of claim 1 but add the limitations that the biomaterial must be freeze-dried and form a powder.

Tu et al. anticipates claim 1 but does not teach freeze-drying or making the biomaterial into a powder. However Kelman et al. teach a chemically modified crosslinkable collagen from a mammal (see abstract) that is freeze dried and ground into a powder (col. 6, lines 25-30). Once in the powdered state the powdered collagen can be shaped into an implant (col. 10, lines 50-60) such as a skin replacement (col. 12, lines 33-45) or graft.

It would have been obvious to someone skilled in the art to combine the inventions of Tu et al. with Kelman et al. with the motivation that both share common goals of producing a collagen based tissue graft with crosslinked collagen. The

reasonable expectation of success is provided by Kelman who indeed does produce implants from their powdered form of crosslinked collagen.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. (WO 94/17841) as applied to claims 1-4, 7, 8, 10, 11 and 13 above, and further in view of Kelman et al. (U.S. Patent 5,067,961, 1991 referred to as '961) and Noishiki et al. (U.S. Patent 4,806,595, 1989).

Claim 9 limits the polyepoxy compound of claim 1 to polyglycerol polyglycidyl ether or polyethylene glycol glycidyl ether. Why Tu et al. does not specifically teach these to compounds he does teach other polyepoxides such as glycol diglycidyl ether, polyol polyglycydyl ether dicarboxylic acid diglycidyl ester, Ethylene glycol diglycidyl ether, Glycerol Triglycidyl ether and Sorbitol tetraglycidyl ether. These are common cross linking agents for collagen and are also used by '961 (see col. 9, lines 25-30) and Noishiki et al.(see col. 2, lines 25-30) who use polyglycerol polyglycidyl ether, diglycerol polyglycidyl ether, glycol diglycidyl ether, polyol polyglycidyl ether, dicarboxylic acid diglycidylester to crosslink collagen. Therefore the polyepoxides listed in claim 9 are art recognized equivalents for the same purpose to those used by Tu et al. and it would be obvious for one of ordinary skill in the art to substitute one polyepoxide in Tu et al. with one from either '961 or Noishiki et al. (M.P.E.P. § 2144.06).

Therefore the references listed above renders obvious claim 9.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached during regular business hours, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1651

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